REMARKS

Claims 1-30, 32-38 and 40 remain pending in the application, of which claims 1, 30, 32, 38 and 40 are presently amended. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

Claim Objections

Claim 38 has been amended to now correctly depend on claim 32. In view of this correction to claim 38, the objection to the claims is believed overcome.

Claim rejections – 35 U.S.C. §112

Claims 1-30, 32-38 and 40 stand rejected under 35 U.S.C. §112 first paragraph, as allegedly falling to comply with the written description requirement. Applicant respectfully traverses this rejection. The claim limitation of "an active element having a pre-deployment configuration carried entirely within the lumen with no portion of the pre-deployed active element located outside of the lumen" is fully supported throughout the written description of the invention. For example, the following paragraphs of the specification disclose:

Paragraph 25: "an agent carrier 14 carried by the coil 12" where the coil 12 includes one or more loops or windings 18, and "the loops 18 define a *central lumen 20 in which the agent carrier 14 is placed*".

Paragraph 31: "As shown in FIG. 1, *the agent carrier 14* includes one or more *axially oriented elements 30* having a substantially rectilinear or a curvilinear (less than 360°) configuration along a length of the vaso-occlusive device 10."

Paragraph 33: "In another embodiment, the axially oriented element 30 is not secured to the coil 12, but is simply *disposed within the lumen 20* of the coil 12"

Paragraph 34: "In one embodiment, the cross-sectional dimension of the agent carrier 14 is approximately 0.002 inch less than the internal diameter of the coil 12. However *any diameter smaller than the coil internal diameter may also be used*."

Paragraph 37: "An advantage of *placing the agent carrier 14 within the lumen 20 of the coil 12* is that an exterior of the coil 12 is unaffected by the bioactive material during delivery of the coil 12."

Paragraph 49: "As shown in FIG. 2... The axially oriented element 30 is *located within the lumen* 220 of the coil 212"

As can be seen from the quoted passages above, throughout the specification and as depicted in Figures 1, 2, 4-6, which also constitute the written description of the invention, the agent carrier or active element is being carried entirely within the lumen with no portion of the pre-deployed agent carrier or active element located outside of the lumen. Applicant respectfully request withdrawal of the §112 objection.

Claim Rejections - 35 U.S.C. §102 (e)

Claims 1, 2, 4-7, 10, 12, 14-17, 19, 20, 30, 32-34 and 40 stand rejected under 35 U.S.C. §102(e), as allegedly being anticipated by USP 6,616,617 ("Ferrera"). Claims 1-5, 14-16, 19, 20, 24, 28, 29, 32, 33, 36 and 40 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by USP 6,193,728 ("Ken"). Applicant respectfully requests reconsideration and withdrawal of these rejections in view of the amendments made to the claims herein.

In order to sustain a rejection under § 102(e), the respective reference must disclose each and every element of the claim, either expressly or inherently. MPEP § 2131. Applicant respectfully submits that Ferrera and Ken cannot support a § 102(e) rejection, because neither reference discloses each and every element of the rejected claims.

Independent claims 1 and 40 each recite "an elongate occlusive member defining a longitudinal axis and having an elongate axial lumen", a limitation that is not disclosed or suggested by Ferrera. In contrast, Ferrera discloses an occlusive device comprising a multi-stranded microcables with a ***central core strand*** surrounded by peripheral twisted or bounded strands or wires (Figs. 1, 2, 9-16 and Col 4 line 40 – Col 5, line 45, Col 10, and lines 6-46). Applicant respectfully disagrees with the Examiner's statement that the element No. 14 *"core wire"* of Figures 1 and 2, and element No. 48 (the *"therapeutic agent"* of Figure 10 of Ferrera) comprise lumens where such elements (14 and 48) are situated. A lumen is an inner **open space** or cavity of a tubular member as indicated in the below definitions. However, Ferrera discloses a core strand tightly surrounded by wires with no open space or lumen between them. Therefore the elongated axial lumen limitation of claims 1 and 40 of the present invention is lacking in Ferrera.

Lumen –*Dictionary.com Unabridged (v 1.1) - Cite This Source*
1. Canal, duct, or cavity of a tubular organ.
2. The inner open space or cavity of a tubular organ, as of a blood vessel.
3. The central space within a tube-shaped body part or organ, such as a blood vessel or the intestine.

Additionally, independent claims 30 and 32 have been amended to more clearly define the axial lumen as extending through the interior regions of the respective adjacent loops forming the coil. The hydrogel of claim 30 or the active element of claim 32 have a

pre-deployment configuration carried entirely within the lumen, wherein the lumen extends through the interior regions of a plurality of adjacent loops that form a helically wound coil. Even if the therapeutic agent of Ferrera is located within a "lumen" (opening for 14 according to the office action interpretation, which Applicant disagrees - see above), such "lumen" of Ferrera does not extend through the interior regions of a plurality of adjacent loops that form a coil. Ferrera does not disclose or suggest such limitation; instead, Ferrera's "lumen" extends within the multistraded microcables that form the wire that is itself wound into loops to form a coil.

Furthermore, the active element claimed in the present invention (claims 1, 32, 40) or hydrogel (claim 30) expand or contract when placed in a body **without the application of a mechanical force**. Additionally, the hydrogel of claims 30 and the active element of claim 32 **radially** expand or contract, respectively. Even if Ferrera's therapeutic agent may expand and contract when placed in the body (Applicant does not concede that it may do so since the therapeutic agent 48 of Fig. 10 is tightly surrounded by twisted or bounded strands or wires with insufficient space -lack of lumen- for at least expansion), such "expansion" or "contraction" will not be radially significant from the original diameter of the therapeutic agent 48, nor will it be accomplished without application of a mechanical force as stated in the amended claims. According to the office action, the therapeutic agent of Ferrera somehow *inherently* expands and contracts as it is twists and bends into the deployed configuration, if so, the twisting and bending of the therapeutic agent is caused by mechanical forces.

Ken does not disclose or suggest that the stretch resistant member, or active element according to the office action, will radially expand or contract. However,

according to the Examiner's interpretation, if the stretch resistant member of Ken does expand or contract, this would be caused by a mechanical force. Also, there is no mention in Ken that the stretch resistance member will expand or contract to cause the occlusive member or coil to retain its shape or stiffen in-situ. Therefore, the limitations of claims 1, 30, 32 and 40 are not disclosed or suggested by Ferrera or Ken.

For the same reason that independent claims 1, 30, 32 and 40 are now believed to clearly define patentable subject matter over Ferrera and Ken, dependent claims 2, 4-7, 10, 12, 14-17, 19, 20, 24, 28-29, 33, 34 and 36 are also believed patentable over Ferrera and Ken, and Applicant respectfully requests that the claim rejections under 102 (e) be withdrawn.

Claim Rejections - 35 U.S.C. §103

Claims 6, 7, 10, 12, 30, 34 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view of Ferrera. Claims 7-9, 11, 13, 18, 21-29, 35-38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ferrera in view of US Pub No. 2001/0046518 ("Sawhney"). Claims 8, 9, 11, 13, 21-29, 35-38 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ken in view of Ferrera, and as applied to claims 6, 7, 10, 12 and 34 in further view Sawhney. Thus, each of the claim rejections under §103 are based at least in part on Ferrera or Ken. Dependent claims 6-13, 18, 21-29, 34, 35-38 incorporates all of the limitations of their respective independent claims as amended, and is therefore allowable for at least the same reasons as claim 1 and 32. Therefore, Applicant respectfully submits that a prima facie case of obviousness based on the cited references has not been established. In

view of the above, Applicant respectfully requests that the Examiner reconsider and withdraw the obviousness rejection.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant respectfully requests a notice of allowance. If there are any questions concerning this amendment and response, please contact the undersigned at the number below.

Respectfully submitted,
VISTA IP LAW GROUP LLP

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By: /David T. Burse/
David T. Burse
Reg. No. 37,104

Customer Number
41696
PATENT TRADEMARK OFFICE

VISTA IP LAW GROUP LLP
12930 Saratoga Avenue, Suite D-2
Saratoga, CA 95070
Phone (408) 777-2905
Fax (408) 877-1662